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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,659	05/11/2001	Steven M. Ruben	PZ003P4	5111

22195 7590 04/23/2002

HUMAN GENOME SCIENCES INC
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EXAMINER

PAPPU, SITA S

ART UNIT PAPER NUMBER

1636

DATE MAILED: 04/23/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/852,659

Applicant(s)

RUBEN ET AL.

Examiner

Sita Pappu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 11, 13, 17-19 and 24-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 11, 13, 17-19 and 24-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Preamendment filed by the Applicant in paper # 9 on 02/15/2002 has been entered. Claim 17 has been amended. Claims 2-10, 12, 14-16, 20-23 are cancelled. New claims 24-75 have been entered. Currently, claims 1, 11, 13, 17-19, 24-75 are pending in the instant application.

Election/Restrictions

The previous restriction requirement mailed on 01/15/2002 is withdrawn in favor of the following restriction.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-39: Claim 1, drawn to an isolated nucleic acid molecule of SEQ ID

Nos: 11,12, 39, 13, 40, 14, 15, 41, 16, 17, 18, 19, 42, 20, 21, 22, 23, 43,
24-27, 44, 28, 45, 29, 46, 47, 30, 48, 32-34, 50, 35, 36, 51, 37, 38,
classified in class 536, subclass 23.

Groups 40-78: Claims 11, 24-75, drawn to an isolated polypeptide, and to a
composition, classified in class 514, subclass 2+.

Group 79: Claim 13, drawn to an antibody, classified in class 530, subclass
387.1+.

Group 80: Claims 18, drawn to gene therapy for treating a medical condition
and a method of diagnosing a pathological condition, classified in
class 514, subclass 44.

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Group 81: Claims 17, 19, drawn to protein therapy for treating a medical condition and a method of diagnosing a pathological condition, classified in class 514, subclass 2.

Claim 1 encompasses the Inventions of Groups 1-39. Should one of these Groups be elected, claim 1 will be examined only to the extent it encompasses the elected subject matter.

Claims 11, 24-75 encompass the Inventions of groups 40-78. Should one of these Groups be elected, claims 11, 24-75 will be examined only to the extent they encompass the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Groups 1-39 are directed to a nucleic acid, while Groups 40-78 are directed to an isolated polypeptide, and, thus, are distinct from each other. Peptides and nucleic acids are substantially different in terms of structural, chemical, physical and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be synthesized or purified from cells.

Group 79 is directed to an antibody and involves methods and protocols that are materially different from Groups 1-78. Further, nucleic acids, proteins and antibodies exhibit different structure and properties.

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Groups 80 and 81 are directed to gene therapy and protein therapy respectively and involve methods that are materially different from each other and from those of Groups 1-79. Groups 80 and 81 differ from each other in that proteins and nucleic acids, which are the starting materials of Groups 80 and 81, are substantially different in terms of structural, chemical, physical and biological properties, and are made using substantially different techniques. Further, the dosages, modes and frequency of administrations and their compositions are different.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Sequence Election

Each of the DNAs and encoded polypeptides of Groups 1-39 and 40-78, respectively, have differing structure and function and therefore do not form a proper Markush group. Therefore, each sequence is placed in its own group because each sequence is patentably distinct one from the other.

Claim 1 is directed to an isolated nucleic acid molecule of SEQ ID NO:X, wherein SEQ ID NO: X comprises the SEQ ID Nos: 11, 12, 39, 13, 40, 14, 15, 41, 16, 17, 18, 19, 42, 20, 21, 22, 23, 43, 24-27, 44, 28, 45, 29, 46, 47, 30, 48, 32-34, 50, 35, 36, 51, 37, 38.

Claim 11 is directed to an isolated polypeptide of SEQ ID NO: Y, wherein SEQ ID NO: Y comprises the SEQ ID Nos: 52, 53, 80, 54, 81, 55, 56, 82, 57-60, 83, 61-64, 84, 65-68, 85, 69, 86, 70, 87, 88, 71, 89, 73-75, 91, 76, 77, 92, 78, 79.

Claims 24-75 are directed to an isolated protein or composition of SEQ ID NO:85 or SEQ ID NO: 68 contained in ATCC deposit No. 209070.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence for prosecution on the merits to which the claims shall be restricted. Applicant is advised that a reply to this requirement must include an identification of the sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the sequences are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the sequences to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (8:30 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305 1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308 4242 for regular communications and (703) 872 9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

S. Pappu
April 22, 2002


ANNE-MARIE BAKER
PATENT EXAMINER